IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

KATHERINE L. HALL

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-08186

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Omnibus Motion *in Limine*)

Pending before the court is Boston Scientific Corporation's Omnibus Motion *in Limine* [Docket 147]. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**. Specifically, individual motions *in limine* 1, 3, 9, 13, 14, 15, and 16 are **GRANTED**, and motions *in limine* 2, 4, 5, 6, 7, 8, 10, 11, 12, 17, and 18 are **DENIED**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 15,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Katherine Hall, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"), a mesh product manufactured by BSC to treat SUI. (*See* Second Am. Short Form Compl. [Docket 109], at 3). Ms. Hall received her surgery at Gundersen Lutheran Hospital in La Crosse,

Wisconsin, on October 12, 2006. (Pl. Fact Sheet [Docket 59-2], at 6). She now claims that as a result of the implantation of the Obtryx, she has developed various complications, including mesh erosion, lower abdominal pain, pelvic pressure, burning sensations, and renewed SUI. (*See id.* at 7). The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; and fraudulent concealment. (*See* Second Am. Short Form Compl. [Docket 109] ¶ 13).[1] The instant omnibus motion *in limine* involves BSC's efforts to exclude or limit certain evidence, arguments, and testimony at trial. I address each motion in turn.[2]

II. Motion *in Limine* 1 – To Preclude Any Evidence or Argument Regarding Fraud on the FDA or Alleged Misbranding

BSC seeks to preclude any evidence of fraud on the FDA or alleged misbranding, particularly through the plaintiff's proffered regulatory expert, Dr. Peggy Pence. The plaintiff concedes that she will not offer evidence of fraud on the FDA or misbranding, including from Dr. Pence. Accordingly, BSC's motion *in limine* is **GRANTED**.

III. Motion *in Limine* 2 – To Preclude Evidence Concerning Material Safety Data Sheets ("MSDS")

BSC seeks to preclude any evidence concerning the Phillips Sumika MSDS, specifically the Marlex Polypropylene MSDS containing a Medical Application Caution ("the Caution"). BSC argues that the MSDS is irrelevant, misleading to the jury, unfairly prejudicial, and would result in an undue delay and waste of time. I find BSC's arguments wholly unconvincing. First,

[1] By Memorandum Opinion and Order entered on February 27, 2015, [Docket 157], this court dismissed the plaintiff's claims for manufacturing defect, strict liability for failure to warn, negligent failure to warn, breach of express and implied warranties, and fraudulent concealment. Thus, the remaining claims are strict liability for design defect and negligent design.

[2] The court's choice-of-law analysis is provided in its Memorandum Opinion and Order entered on February 27, 2015, [Docket 157].

BSC contends that the plaintiff should be precluded from offering any evidence related to the MSDS because such evidence is irrelevant to the plaintiff's claims and will mislead the jury. BSC bases this contention on the deposition testimony of Frank Zakrzewski, corporate representative for Chevron Phillips Chemical Company.

Evidence or argument as to the methods by which BSC acquired polypropylene resin is relevant to both the plaintiff's substantive claims and claims for punitive damages. *See In re C. R. Bard, Inc.*, MDL No. 2187, 2013 WL 3282926, at *3 (S.D. W. Va. June 27, 2013) (denying Bard's motion *in limine* seeking to preclude evidence concerning the same MSDS); *see also Sanchez v. Boston Scientific Corp.*, ___ F. Supp. 2d ___, *1 (S.D. W. Va. 2014) (denying BSC's motion for partial summary judgment on the plaintiffs' punitive damages claims), *available at* 2014 WL 4059214. The MSDS served as a notification to BSC of the manufacturer's concerns about the safety of its product for permanent implantation in the human body. Furthermore, the Caution in the MSDS is pertinent to BSC's knowledge of potential safety concerns in its final product.

BSC attempts to bolster its argument by relying on a deposition that is both vague and unclear. BSC contends that Mr. Zakrzewski unequivocally states that the Caution was not added based on any scientific concerns. However, BSC's particular reading of Mr. Zakrzewski's testimony is not an accurate reflection of his opinions. Mr. Zakrzewski clearly indicates he has no knowledge of who wrote the MSDS or why it was written. (*See* Zakrzewski Dep. [Docket 153-2], at 183 ("Q: . . .[Y]ou answered you don't know why the statement, the medical caution statement was added to the MSDS? . . . . A: Yes. . . . . Q: There's no scientific basis for the statement in the MSDS? . . . . A: That would be speculation. I don't know.")). BSC improperly

conflates Mr. Zakrzewski's lack of knowledge regarding scientific testing with a conclusive determination. I have made it clear in this MDL that I find the MSDS to be sufficiently relevant, and BSC's arguments do not change my mind. Accordingly, BSC's motion *in limine* is **DENIED**.

IV. Motion *in Limine* 3 – To Preclude Evidence Concerning Polyethylene Material Safety Data Sheets

BSC seeks to preclude evidence concerning the polyethylene MSDS because it is irrelevant. I have previously reviewed an identical motion *in limine* in *Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5445769, at *2 (S.D. W. Va. Oct. 22, 2014). To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Tyree*, I ruled as follows:

> BSC explains that BSC employees and consultants responded to questions concerning the polyethylene material safety data sheet ("MSDS") thinking they were responding to questions concerning the polypropylene MSDS. The plaintiffs attempt to highlight the fact that the polyethylene MSDS was written in 2001, three years before the polypropylene MSDS. (Pls.' Omnibus Resp. [Docket 395], at 4). However, BSC clearly states that polyethylene is not a material used in BSC's mesh. (*Id.* at 8; BSC's Reply in Supp. of Its Mot. to Preclude Evidence Concerning Polyethylene MSDSs [Docket 438], at 1). Evidence related to materials not present in the device at issue is clearly outside the scope of the plaintiffs' claims and irrelevant. Accordingly, BSC's motion *in limine* on this issue is **GRANTED**.

Id. Therefore, I **ADOPT** my prior ruling on this issue, as stated in *Tyree*, and **GRANT** BSC's motion *in limine*.

V. Motion *in Limine* 4 – To Preclude Evidence of BSC's Procurement of Polypropylene Resin

BSC seeks to preclude evidence of BSC's procurement of polypropylene resin, particularly purchases from a Chinese distributor in 2011. I **FIND** that evidence as to the

methods by which BSC acquired polypropylene resin is potentially relevant as to the plaintiff's substantive claims, as well as claims for punitive damages. However, an evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* is **DENIED**.

VI. Motion *in Limine* 5 – To Preclude Evidence Regarding the ProteGen Device

BSC seeks to preclude evidence regarding the ProteGen device because it is irrelevant, misleading to the jury, unfairly prejudicial, and will result in an undue delay and waste of time. I have previously reviewed an identical motion *in limine* in *Tyree*. 2014 WL 5445769, at *3. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Tyree*, I ruled as follows:

> In *Lewis*, I excluded evidence regarding the recall of the ProteGen sling because it would require extensive discussion of the FDA 510(k) clearance process, given that Ethicon used the ProteGen as a regulatory predicate device. *See id.* ("A discussion of the 510(k) process, whether in the context of the clearance of a new device or the recall of a predicate product, presents the danger of unfair prejudice and confusing the jury."). Here, BSC did not use the ProteGen as a regulatory predicate device, a fact that BSC itself points out in its Memorandum in Support. (*See* Def.'s Mem. Supp. [Docket 375], at 12). The ProteGen was a product that BSC developed, sold, and subsequently recalled. (Pls.' Omnibus Resp. [Docket 395], at 7). An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. The context in which the plaintiffs seek to introduce evidence of the ProteGen is clearly different than that of the Ethicon trial. However, I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

Id. Therefore, I **ADOPT** my prior ruling on this issue, as stated in *Tyree*, and **DENY** BSC's motion *in limine*.[3]

VII. Motion *in Limine* 6 – To Preclude Any Evidence or Argument Concerning BSC's Intent, Motives, or Ethics

BSC seeks to preclude any evidence concerning BSC's intent, motives, and ethics because it is irrelevant, unfairly prejudicial, an undue waste of time, and beyond the scope of the plaintiff's experts' knowledge. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* is **DENIED**.

VIII. Motion *in Limine* 7 – To Preclude Any Evidence or Argument Concerning Foreign Regulatory Actions

BSC seeks to exclude any evidence concerning foreign regulatory actions on BSC's pelvic mesh products. BSC argues that such evidence is irrelevant because the plaintiff's BSC product was implanted in the United States. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* is **DENIED**.

IX. Motion *in Limine* 8 – To Preclude Any Evidence or Argument Concerning BSC's Post-Implant Product Innovations, Including Obtryx II, LITE Mesh and Colored Mesh

[3] This finding is limited by my exclusion of any evidence related to the FDA 510(k) clearance process and enforcement.

BSC seeks to preclude evidence of subsequent changes or new product lines developed by BSC after Ms. Hall's implant date. BSC argues that such evidence is inadmissible as a subsequent remedial measure and irrelevant. Although it appears that BSC's motion has merit, as evidence relating to other devices is outside the scope of the plaintiff's design defect claim, this issue would be better handled at trial, as evidence is presented. Furthermore, evidence of subsequent remedial measures that is inadmissible to prove "negligence; culpable conduct; a defect in a product or its design; or a need for warning or instruction," may be admitted "for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." Fed. R. Evid. 407. In other words, the admissibility of such evidence or argument depends on the context and method by which the plaintiff seeks to introduce it. Accordingly, BSC's motion *in limine* is **DENIED**.

X. Motion *in Limine* 9 – To Preclude Any Evidence or Argument that BSC Owed or Breached a Duty to Warn Ms. Hall Directly

BSC seeks to preclude any evidence that BSC owed or breached a duty to warn the plaintiff directly. I have recently dismissed Ms. Hall's strict liability and negligent failure-to-warn claims. (*See* Memo. Op. & Ord. [Docket 157], at 15). Any evidence or argument that BSC owed or breached a duty to warn the plaintiff directly is therefore irrelevant, and BSC's motion *in limine* is **GRANTED**.

XI. Motion *in Limine* 10 – To Preclude Any Evidence or Argument that BSC Owed or Breached a Duty to Train Plaintiff's Physicians

BSC moves to preclude evidence that BSC owed or beached a duty to train the plaintiff's physicians as irrelevant because the plaintiff has not asserted claims against the implanting physician and BSC argues Wisconsin does not recognize a duty to train a physician. I have

previously denied a similar motion in the face of similar reasons. In *Tyree*, I ruled that regardless of whether West Virginia recognizes a duty to provide training to physicians, evidence or argument related to physician training might possibly be relevant for some other purpose, depending on the context and method by which it is introduced. 2014 WL 5445769, at *5. I see no reason to deviate from this ruling here. Therefore, BSC's motion *in limine* is **DENIED**.

XII. Motion *in Limine* 11 – To Preclude Any Evidence or Argument Concerning Marketing and Promotional Materials Not Seen by Ms. Hall or Her Implanting Physician

BSC seeks to exclude marketing materials not seen by Ms. Hall or her implanting physician because they are irrelevant, unfairly prejudicial, and potentially confusing to the jury. I have rejected this argument before, finding that "[t]hese materials *may* be relevant to the plaintiffs' other claims, including negligence and punitive damages." *Bard*, 2013 WL 3282926, at *6 (emphasis added). This finding applies here, where the plaintiff has claimed negligent design and has asked for punitive damages. Further disputes about relevancy can be addressed at trial, when the content and proffered use of the materials is apparent. Thus, BSC's motion *in limine* is **DENIED**.

XIII. Motion *in Limine* 12 – To Preclude Product Complaints, Adverse Event Reports, and Medical Device Reports Concerning Patients Other than Ms. Hall

BSC seeks to exclude product complaints, adverse event reports, and medical device reports concerning patients other than Ms. Hall because they are inadmissible hearsay and irrelevant. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of

such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* is **DENIED**.

XIV. Motion *in Limine* 13 – To Preclude Any Evidence or Argument that Pelvic Mesh Can Cause Complications Not Experienced by Ms. Hall

BSC moves to preclude any evidence that mesh can cause complications not experienced by Ms. Hall because it is irrelevant and unfairly prejudicial. Evidence of complications that the plaintiff has not experienced is irrelevant and lacking in probative value. For the claims that require evidence of injury, only the injuries experienced by the complainant are relevant. Strict liability for defective design, for instance, focuses on the plaintiff's injuries. *See* Wis. Stat. § 895.047(1) (2014) (requiring that "the defective condition was a cause of the claimant's damages"). Similarly, with respect to negligent design, the concern is for injuries caused to the claimant. *See Sharp ex rel. Gordon v. Case Corp.*, 595 N.W.2d 380, 388 (Wis. 1999) (noting proof of negligent design requires: "a defect existed that could have been discovered and that failure to discover the defect constituted a breach of a defendant's duty of ordinary care, *thereby causing a plaintiff's injuries*" (emphasis added)). Accordingly, evidence that the Obtryx causes injuries not experienced by the plaintiff has little value. Moreover, elaborating on injuries that the plaintiff did not incur risks "needless presentation of cumulative evidence." Fed. R. Evid. 403. Therefore, BSC's motion *in limine* is **GRANTED**.

XV. Motion *in Limine* 14 – To Preclude Any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Pelvic Mesh Products

BSC seeks to exclude evidence of lawsuits against other manufacturers of pelvic mesh because it is irrelevant, unfairly prejudicial, and will mislead the jury. Pointing to my previous ruling in *Bard*, the plaintiff counters that disputes about admissibility of this evidence should be

reserved for trial to the extent BSC opens the door on this issue. The use of motions *in limine* that lack specificity and are without context have led the court in the past to defer judgment on several evidentiary issues, including this one. *See Bard*, 2013 WL 3282926, at *2. Having gained greater familiarity, however, the court was confident in substantively ruling on the admissibility of other lawsuits against the same defendant in *Lewis v. Ethicon, Inc.*:

> [E]vidence of lawsuits is generally considered inadmissible hearsay. . . . Further, evidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the [product] is defective, the jury must still find that the [product] caused [the plaintiff's] injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to [the defendant].

No. 2:12-cv-4301, 2014 WL 505234, at *6 (S.D. W. Va. Feb. 5, 2014). I find this rationale, as applied to exclude lawsuits against the *same* defendant, to be exceedingly appropriate here, where the plaintiff seeks to introduce evidence of lawsuits against *other* manufacturers. Even assuming evidence about lawsuits brought against other manufacturers has some relevance to the present case, the relevance is dwarfed by the risk of unfair prejudice posed by requiring BSC to attest for lawsuits in which it was not involved. Accordingly, pursuant to Rule 403, I **GRANT** BSC's motion *in limine*.

XVI. Motion *in Limine* 15 – To Preclude Any Evidence or Argument Concerning Other Mesh Lawsuits, Investigations, Claims, Verdicts, and Trials Against BSC

BSC seeks to exclude evidence of other mesh lawsuits, investigations, claims, verdicts, and trials against BSC because it is irrelevant, inadmissible hearsay, and unfairly prejudicial. I granted a motion *in limine* in *Lewis* to exclude evidence of other mesh lawsuits against the defendant. *See* 2014 WL 505234, at *5–6. I noted that "evidence of lawsuits is generally

considered inadmissible hearsay[,]" and ultimately excluded the evidence on Rule 403 grounds. I explained:

> [E]vidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the [product] is defective, the jury must still find that the [product] caused [the plaintiff's] injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to [the defendant]. Accordingly, Ethicon's motion on this issue is **GRANTED**.

Id. I apply this reasoning to the evidence challenged by BSC here. Therefore, I **GRANT** BSC's motion *in limine*.

XVII. Motion *in Limine* 16 – To Preclude Any Evidence or Argument Concerning Unrelated FDA Corporate Warning and 483 Letters, All Pertaining to Cardiac Devices

BSC seeks to exclude a 2006 corporate warning and FDA 483 letters concerning cardiac devices because they are irrelevant, improper character evidence, and unfairly prejudicial. The plaintiff responds these pieces of evidence are relevant because they broadly refer to company-wide policies and processes. The plaintiff also contends she should be able to introduce this evidence to rebut positive character evidence BSC might offer. This evidence has little to no probative value for the plaintiff's claims regarding pelvic mesh, specifically the Obtryx, and has significant potential to unfairly prejudice BSC, confuse the issues, or mislead jury. Accordingly, BSC's motion *in limine* is **GRANTED**.

XVIII. Motion *in Limine* 17 – To Preclude Any Evidence or Argument Concerning Parties' Litigation Conduct

BSC seeks to exclude evidence of the parties' litigation conduct. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time

without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, BSC's motion *in limine* is **DENIED**.

XIX. Motion *in Limine* 18 – To Preclude Any Evidence or Argument Concerning BSC's Finances or Employment Decisions

BSC seeks to exclude evidence of BSC's net worth, profits, employee compensation, and other employment issues because it is irrelevant and unfairly prejudicial. I have previously reviewed an identical motion *in limine* in *Tyree*. 2014 WL 5445769, at *9. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Tyree*, I ruled as follows:

> BSC argues that the plaintiffs are attempting to "[paint] [BSC] as a bad actor improperly motivated by profit" and "induce the jury to render a verdict simply because Boston Scientific is a large company with significant resources[.]" (*Id.* at 46–47). I note that I denied BSC's motion for summary judgment on the issue of punitive damages. (*See* Mem. Op. & Order [Docket 425]). Therefore, consistent with my finding in *Bard*, I **FIND** that evidence of BSC's finances or employment decisions may be relevant as to the amount of punitive damages. *See* 2013 WL 3282926, at *15. Furthermore, to the extent that certain financial information "[paints] [BSC] as a bad actor improperly motivated by profit," it may be relevant to the question of liability for punitive damages. *See id.* at 12, 15 (denying Bard's motions *in limine* as to Bard's financial information or condition *and* as to Bard's intent, motives, and ethics). Accordingly, BSC's motion *in limine* on this issue is **DENIED without prejudice**.

Id. Wisconsin law mirrors this analysis, providing that "[i]f the plaintiff establishes a prima facie case for the allowance of punitive damages . . . [t]he plaintiff may introduce evidence of the wealth of a defendant." Wis. Stat. § 895.043. At this time, the punitive damages claim still exists in this case. Therefore, I **ADOPT** my ruling in *Tyree* on this issue and **DENY without prejudice** BSC's motion *in limine*.

XX. Conclusion

For the reasons set forth above, Boston Scientific Corporation's Omnibus Motion *in Limine* [Docket 147] is **GRANTED in part** and **DENIED in part**. Specifically, individual motions *in limine* 1, 3, 9, 13, 14, 15, and 16 are **GRANTED**, and motions *in limine* 2, 4, 5, 6, 7, 8, 10, 11, 12, 17, and 18 are **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 27, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE